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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM E. KLUNK, CHESTER A. MATHIS, JR.,
and YANMING WANG

Appeal[1] 2009-007431
Application 10/645,847
Technology Center 1600

Decided: April 27, 2010

Before ERIC GRIMES, JEFFREY N. FREDMAN, and
STEPHEN WALSH, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Oral hearing held April 22, 2010.

This is an appeal under 35 U.S.C. § 134 involving claims to benzothiazole derivative compounds. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

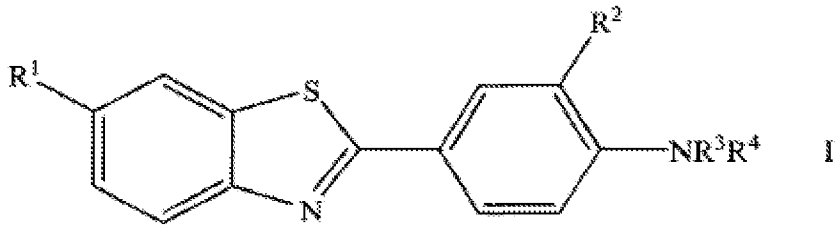
"Studies suggest that amyloid deposition in the brain is an early, causative event in the pathogenesis of Alzheimer's disease (AD)" (Spec. 1, ll. 2-3). The Specification teaches that "[s]ince the initial deposition of amyloid may occur long before clinical symptoms of AD are noticeable, the detection and quantitation of amyloid deposits could facilitate the diagnosis of AD in its early, pre-symptomatic stages" (Spec. 1, ll. 8-10).

"The inventive compound may be used to determine the presence, location and/or amount of one or more amyloid deposit(s) in an organ or body area, including the brain, of an animal." (Spec. 7, ll. 12-14.)

The Claims

Claim 1 is on appeal. Claim 1 reads as follows:

1. A compound of formula I



I

or a pharmaceutically acceptable salt, hydrate, solvate or prodrug of the compound, wherein:

> R^1 is hydrogen, -OH, -NO_2, -CN, -COOR, -OCH_2OR, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_1-C_6 alkoxy or halo;
>
> R is C_1-C_6 alkyl;
>
> R^2 is a non-radioactive halo or a radioactive halo;
>
> R^3 is hydrogen, C_1-C_6 alkyl, C_2-C_6 alkenyl or C_2-C_6 alkynyl; and
>
> R^4 is C_1-C_6 alkyl, C_2-C_6 alkenyl or C_2-C_6 alkynyl, wherein the alkyl, alkenyl or alkynyl comprises a radioactive carbon or is substituted with a radioactive halo when R^2 is a non-radioactive halo.

The prior art

The Examiner relies on the following prior art reference to show unpatentability:

Klunk et al.	US 7,270,800 B2	Sep. 18, 2007

The issue

The Examiner rejected Claim 1 on the ground of nonstatutory obviousness-type double patenting over Claim 4 of U.S. Patent 7,270,800 (Ans. 4-6).

The Examiner finds that "both sets of claims are directed to products having a radiolabeled halogen. The claims differ in that those of the patented invention do not limit the location of the radiolabeled halogen" (Ans. 4). The Examiner finds that

> a skilled artisan would recognize that since both sets of claims require a radioisotope (i.e., radiohalogen) and the radioisotopes of the patented invention are not limited to any particular location, the skilled artisan would recognize that it is within the skill of an ordinary practitioner in the art to have a radioactive halogen at position R2 because Compounds 4, 8, 12, 16, 20, and 39 of the patented

> invention all contain a halogen in the R2 position and fulfill the requirements of the other variables (R1, R3, and R4) of the instant invention.

(*Id.*)

Appellants argue that "the choices of (1) a specific halogen isotope and (2) the position on a benzothiazole where that isotope is to reside give rise to myriad possible combinations of (1) and (2)" (App. Br. 10). Appellants argue that "[t]he PTO's analysis fails to account for a much larger group of compounds that fall *outside the scope of rejected claim 1* by virtue of radiohalogen substitution occurring at positions other than present R^2" (*id.*). Appellants argue that "the PTO's analysis fails to specify why the skilled artisan would first select a benzothiazole in claim 4 of the '800 patent bearing a non-radioactive halogen substituent at the 2- position, corresponding to present R^2" (*id.* at 12). Appellants argue that "[a]s far as Appellants are aware, there is no rule of patent law holding that atom isotopes are *prima facie* obvious variants of each other" (*id.*).

In view of these conflicting positions, we frame the nonstatutory obviousness-type double patenting issue before us as follows:

Does the evidence of record support the Examiner's conclusion that Claim 1 is not patentably distinct from Claim 4 of U.S. Patent 7,270,800?

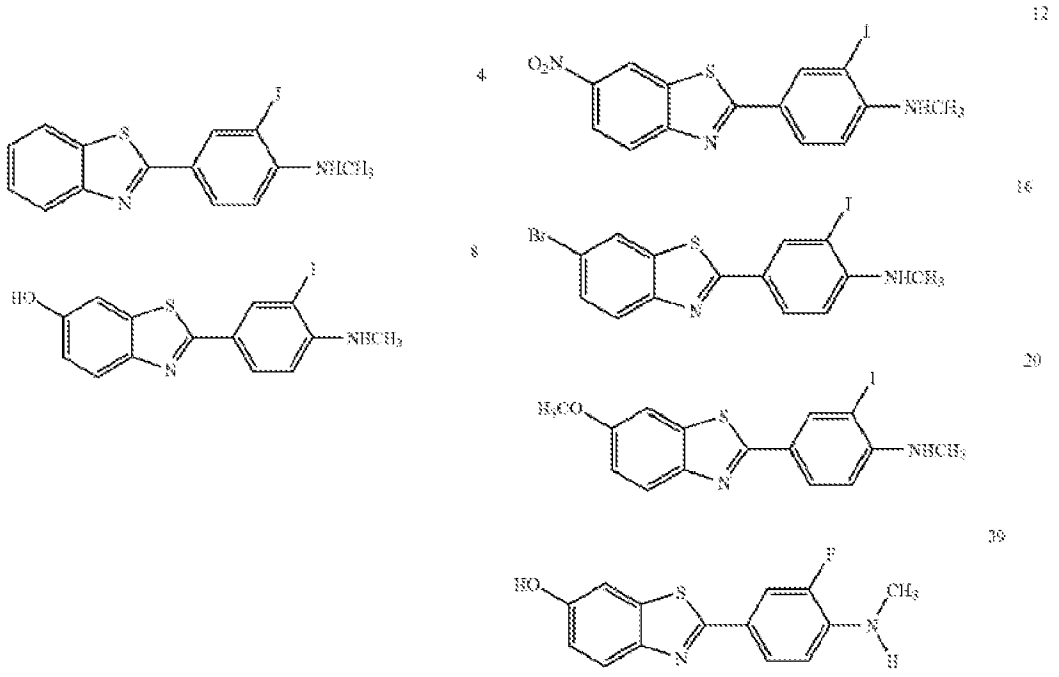
Findings of Fact (FF)

1. The Klunk et al patent, U.S. Patent 7,270,800, was filed on March 14, 2003 as U.S. application 10/388,173 and issued on September 18, 2007.

2. The instant application, U.S. application 10/645,847, was filed on August 22, 2003.

3. Claim 4 of U.S. Patent 7,270,800 is partially reproduced below, with the chemical structures identified as relevant by the Examiner included:

4. A method of synthesizing a compound selected from the group consisting of:



wherein at least one of the atoms in each of the formulae 1-34, 36, and 38-45 is replaced by a member selected from the group consisting of ^{131}I, ^{125}I, ^{123}I, ^{76}Br, ^{75}Br, ^{18}F, and ^{19}F, the method comprising reacting a tri-alkyl tin derivative of a compound according to one of formulae 1-34, 36, and 38-45 with a halogenating agent containing ^{131}I, ^{125}I, ^{123}I, ^{76}Br, ^{75}Br, ^{18}F, or ^{19}F.

Principles of Law

"Obviousness-type double patenting … requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent. Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later." *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998).

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

The Supreme Court has emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Analysis

The dispute centers on whether it would have been obvious, over Claim 4 of U.S. Patent 7,270,800, to place a radioactive halogen in the position which corresponds to R^2 of the compound of formula I in instant Claim 1. That is, is Claim 1 patentably distinct from Claim 4 of U.S. Patent 7,270,800?

Three separate lines of reasoning support the obviousness position of the Examiner.

First, the ordinary artisan is taught by Claim 4 of U.S. Patent 7,270,800 that "at least one of the atoms in each of the formulae 1-34, 36, and 38-45 is replaced by a member selected from the group consisting of ^{131}I, ^{125}I, ^{123}I, ^{76}Br, ^{75}Br, ^{18}F, and ^{19}F." The ordinary artisan of ordinary creativity would reasonably have selected to replace the nonradioactive iodine at the R^2 position in compound 4 of Claim 4 of U.S. Patent 7,270,800 with the radioactive iodine, since this replacement would least affect the chemical properties of the resulting molecule. That is, the ordinary artisan would reasonably infer, for example, that the modification of compound 4 of Claim 4 of U.S. Patent 7,270,800 that minimally would affect the use of that compound would be replacement of the nonradioactive iodine with ^{131}I, ^{125}I, or ^{123}I, a modification expressly suggested by Claim 4 of U.S. Patent 7,270,800.

Second, "[s]tructural relationships often provide the requisite motivation to modify known compounds to obtain new compounds." *In re Mayne*, 104 F.3d 1339, 1343 (Fed. Cir. 1997). The chemical compounds of Claim 4 of U.S. Patent 7,270,800 are extremely similar to those of the instant Claim 1, differing only in that each of the compounds of Claim 4 of U.S. Patent 7,270,800 permits the radioactive halogen to be located at positions other than R^2, as well as the R^2 position. However, "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of

obviousness." *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc). Here, there is both significant structural similarity between the claimed and prior art subject matter, and the prior art of Claim 4 of U.S. Patent 7,270,800 specifically suggests that "at least one of the atoms in each of the formulae 1-34, 36, and 38-45 is replaced by a member selected from the group consisting of ^{131}I, ^{125}I, ^{123}I, ^{76}Br, ^{75}Br, ^{18}F, and ^{19}F."

Third, the relationship of Claim 4 of U.S. Patent 7,270,800 relative to Appellants' Claim 1 is substantially analogous to the situation the Court of Customs and Patent Appeals addressed in *In re Petering*, 301 F.2d 676 (CCPA 1962). In *Petering*, the Court contrasted the effect of the disclosure of a broad generic class of compounds with the disclosure of a limited class of compounds (limited genus). *Id.* at 681. Specifically, the Court held that the disclosure of a broad class of compounds without more is not anticipatory; however, the Court held that the disclosure of a limited class of compounds anticipates all species within that limited genus when a person of ordinary skill in the art would "at once envisage each member" of the limited class. *Id.*

Here, while the instant rejection is based on obviousness and not anticipation, we find it reasonable that one skilled in the art would at once envisage that each of the compounds of Claim 4 of U.S. Patent 7,270,800 has only about 9 possible positions on which the halogens can be substituted (*see* App. Br. 10; "[C]ited compound 2 features at least (9) positions including R^2 where an existing atom can be replaced by one of the halogen isotopes recited by claim 4 of the '800 patent"). Substitution at one of those 9 positions, the R^2 position, would anticipate, and therefore render obvious,

the compound of Claim 1. Further, substitution at that position with any of the radioactive halogens suggested by Claim 4 of U.S. Patent 7,270,800 would satisfy the requirement of instant Claim 1 that the R^2 position comprise a radioactive halo and anticipate. Accordingly, Claim 4 of U.S. Patent 7,270,800 reasonably renders the instant Claim 1 obvious.

Appellants argue that "the choices of (1) a specific halogen isotope and (2) the position on a benzothiazole where that isotope is to reside give rise to myriad possible combinations of (1) and (2)" (App. Br. 10). Appellants argue that "[t]he PTO's analysis fails to account for a much larger group of compounds that fall *outside the scope of rejected claim 1* by virtue of radiohalogen substitution occurring at positions other than present R^2" (*id.*).

We are not persuaded. Simply because some of the compounds rendered obvious by Claim 4 of U.S. Patent 7,270,800 fall outside the scope of the instant Claim 1 does not mean that the claimed subject matter is "patentably distinct from the subject matter claimed in a commonly owned patent." *Berg*, 140 F.3d at 1431. The question is whether Claim 1 is patentably distinct from Claim 4 of U.S. Patent 7,270,800. For the three reasons given above, we conclude that Claim 1 is not patentably distinct from Claim 4 of U.S. Patent 7,270,800.

Appellants argue that "the PTO's analysis fails to specify why the skilled artisan would first select a benzothiazole in claim 4 of the '800 patent bearing a non-radioactive halogen substituent at the 2- position, corresponding to present R^2" (App. Br. 12).

We are not persuaded. The Examiner reasonably concludes that the "obviousness of having a ***radiolabeled*** halogen in that position stems from the fact that the patented claim (see claim 4) discloses that at least one atom in the formula is replaced with a radiolabeled halogen such as 131I, 125I, or 123 halogen, for example" (Ans. 8). This obviousness argument is consistent with the first reason identified above, that the ordinary artisan of ordinary creativity would reasonably have selected to replace the nonradioactive iodine at the R^2 position in compound 4 of Claim 4 of U.S. Patent 7,270,800 with the radioactive iodine, since this replacement would minimally affect the chemical properties of the resulting molecule. Further, the structural similarity reasoning of *Dillon* also supports obviousness. *See In re Dillon*, 919 F.2d at 692.

Appellants argue that "[a]s far as Appellants are aware, there is no rule of patent law holding that atom isotopes are *prima facie* obvious variants of each other" (App. Br. 12).

We agree that there is no *per se* rule of obviousness for isotopes. However, the facts of the instant case provide more suggestion, since Claim 4 of U.S. Patent 7,270,800 expressly teaches that "at least one of the atoms in each of the formulae 1-34, 36, and 38-45 is replaced by a member selected from the group consisting of ^{131}I, ^{125}I, ^{123}I, ^{76}Br, ^{75}Br, ^{18}F, and ^{19}F." It is this express teaching to substitute a radioactive isotope for a different atom on the compounds which renders the claim obvious for the three reasons given above, not due to a *per se* rule.

Conclusion of Law

The evidence of record supports the Examiner's conclusion that Claim 1 is not patentably distinct from Claim 4 of U.S. Patent 7,270,800.

SUMMARY

In summary, we affirm the rejection of Claim 1 on the ground of nonstatutory obviousness-type double patenting over Claim 4 of U.S. Patent 7,270,800.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

cdc

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